

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION  
NO. 5:13-CV-760-BO**

RECKITT BENCKISER  
PHARMACEUTICALS INC., RB  
PHARMACEUTICALS LIMITED, and  
MONOSOL RX, LLC,

Plaintiffs,

v.

BIODELIVERY SCIENCES  
INTERNATIONAL, INC.,

Defendant.

**PLAINTIFFS' RESPONSE  
TO DEFENDANT'S NOTICE  
OF SUPPLEMENTAL  
FILING**

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc., RB Pharmaceuticals Limited, and MonoSol Rx, LLC respectfully submit this response to BDSI's Notice of Supplemental Filing in Support of its Motion to Dismiss, filed late yesterday (D.I. 48) ("Supplement").

BDSI's Supplement mischaracterizes Plaintiffs' position in the Par ANDA litigation pending in Delaware. At no time have Plaintiffs taken the position that BDSI attributes to them. Specifically, it is not Plaintiffs' position in the Par ANDA litigation that a patent infringement action arises under section 271(e)(2) only when the applicant includes a Paragraph IV notice with the application. Rather, it is Plaintiffs' position in the Par ANDA litigation that subject matter jurisdiction in a Paragraph IV, ANDA-filer case only arises if the ANDA filer has complied with the specific procedural requirements of the Hatch Waxman statute relating to Paragraph IV Notices that apply to ANDA filers.

BDSI is not an ANDA filer, so the considerations in the Par ANDA litigation are not relevant in this case. Here, BDSI has circumvented the requirement to serve a Paragraph IV notice letter by relying on the Suboxone® tablet NDA (as to which there are no unexpired patents) instead of the Suboxone® film NDA. Therefore, the specific procedural mechanisms of

the Hatch Waxman statute that relate to Paragraph IV notice letters do not apply in the present BDSI case, and Plaintiffs' position in the Par ANDA litigation has no relevance here for that reason. Rather, there is subject matter jurisdiction over BDSI's section 505(b)(2) NDA filing under section 271(e)(2) in view of the governing Federal Circuit case law discussed in Plaintiffs' Opposition (D.I. 27), as BDSI itself has admitted.

This the 23rd day of April, 2014.

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing and the accompanying Plaintiffs' Suggestion of Subsequently Decided Controlling Authority has been delivered via ECF to the following on this 23rd day of April, 2014:

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